HALT-C Trial Q x Q

Physical Exam

Form # 11 Version A: 06/15/2000 (Rev. 03/20/2002)

Purpose of Form #11: The Physical Exam form records general and physical examination results. Because Form #11 may be used as a source document, data collectors must sign the form.

When to complete Form #11: Form #11 should be completed for all patients at the following visits.

- **Screening Phase:** Screening Phase study visit 1 (S01).
- **Lead-In Phase patients:** Week 12 (W12) and Week 20 (W20).
- **W20 Responder Phase patients:** Week 36 (W36), Week 48 (W48) and Week 72 (W72).
- **Randomized patients**: Every randomized phase study visit.

Some sections and questions on Form #11 are not required at all visits, as described on the form and in the instructions below. The information may still be recorded on Form #11, but the HALT-C Data Management System (DMS) will not expect this data when data entry is performed. The DMS is programmed to automatically skip any questions that are not required.

If no physical examination was done and no data is recorded in Sections B-D, record a brief explanation on the incomplete Form #11. The data entry person should set the Form #11 to missing in the DMS and type the explanation in the "Enter Missing Form Reason" box.

If only a partial physical examination was completed, record a brief explanation on the incomplete Form #11. The data entry person should enter all recorded data and type an explanation in form level and field level comments as necessary.

It is not sufficient to write "Not Done." Explanation examples:
- "Physician unavailable."
- "Pt late for appt., no MD available."

SECTION A: GENERAL INFORMATION

A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.

A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.

A3. Enter the three-digit code corresponding to this visit.

A4. Record the date the physical exam was done using MM/DD/YYYY format.

A5. Enter the initials of the person completing the form.

SECTION B: GENERAL EXAMINATION

Note: The HALT-C staff member who collects the data recorded in **Questions B1 – B5** must sign the form on page 1.

B1. Record the patient's weight at every visit that requires a Form #11.

- Weigh the patient with clothes on and heavy outerwear and shoes off.
- Record the weight in units (kg or lb) that were used on the measuring instrument. It is not necessary to record both kilograms and pounds.
- Round kilograms to 0.1 kg. Round pounds to the nearest lb.

B2. Record the patient's height only on the Screening Phase (S00) Form #11. Skip this question at all other study visits.

- Measure height with shoes off and all headgear removed.
- Record the height in units (cm or in) that were used on the measuring instrument. It is not necessary to record both centimeters and inches.
- Round centimeters to the nearest cm. Round inches to the nearest inch.

- If the patient's height was not recorded on Form #11 at the Screening Visit (S00), it can be measured at a later visit. Record the height on the S00 Form #11 with your initials, date, and a brief explanation. The data entry person should update Question B2 on the S00 Form #11 and add the explanation as a field level comment.

B3. Record the patient's waist circumference at the following three visits. Measurement instructions are provided on the next page of this QxQ.

- Screening Phase: Screening visit 1 (S01).
- Randomized Phase patients: Month 24 (M24) and Month 48 (M48).

- If the patient's waist circumference was not recorded on Form #11 at the S00, M24, or M48 visits, it can be measured up to six months later. Record the waist circumference on the Form #11 with your initials, date, and a brief explanation. The data entry person should update Question B3 on the appropriate S00, M24, or M48 Form #11 and add the explanation as a field level comment.

B4. Record the patient's blood pressure at the following visits:

- Screening Phase: Screening visit 1 (S01).
- Responder Phase patients: Week 36 (W36), Week 48 (W48) and Week 72 (W72).
- Randomized Phase patients: Month 12 (M12), Month 24 (M24), Month 36 (M36), and Month 48 (M48).

- Record systolic and diastolic blood pressure in mmHg.

B5. Record the patient's pulse at the following visits:

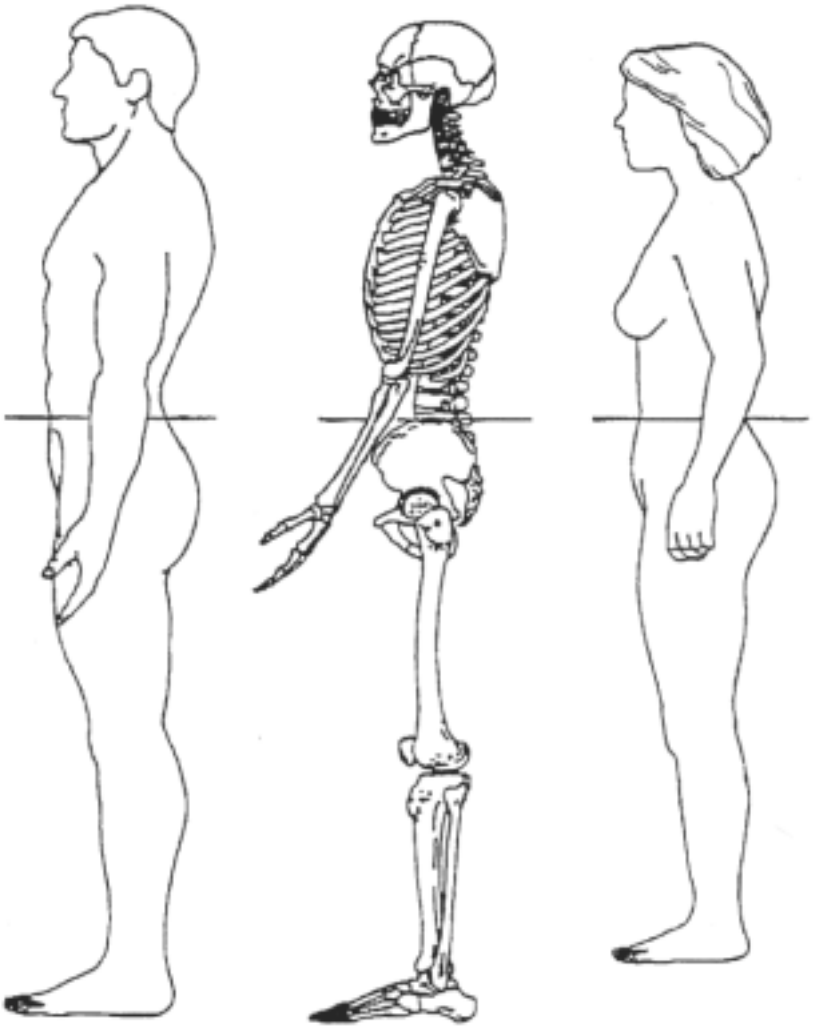
- Screening Phase: Screening visit 1 (S01).
- Responder Phase patients: Week 36 (W36), Week 48 (W48) and Week 72 (W72).
- Randomized Phase patients: Month 12 (M12), Month 24 (M24), Month 36 (M36), and Month 48 (M48).

- Record pulses per minute.

After answering Question B5, sign the form.

Waist Circumference Measurement Instructions

- To define the level at which waist circumference is measured, a bony landmark is first located and marked.
- The patient stands, and the examiner, positioned at the right of the patient, palpates the upper hipbone to locate the right iliac crest. (See figure below.)
- Just above the uppermost lateral border of the right iliac crest, a horizontal mark is drawn, and then crossed with a vertical mark on the midaxillary line.
- The measuring tape is placed in a horizontal plane around the abdomen at the level of this marked point on the right side of the trunk.
- The plane of the tape is parallel to the floor, and the tape is snug, but does not compress the skin.
- The measurement is made at normal minimal respiration.
- Record the circumference in units (cm or in) that were used on the measuring instrument. It is not necessary to record both centimeters and inches.
- Round centimeters to the nearest cm. Round inches to the nearest inch.



Note: The HALT-C staff member who collects the data recorded in **Questions B6 – B20** must sign the form on page 2.

B6 – B20. The physical exam must be done by an MD, NP, or PA affiliated with the HALT-C trial. The findings of the physical exam must be recorded at the study visits listed below.

- Screening Phase: Screening visit 1 (S01).
- Responder Phase patients: Week 36 (W36), Week 48 (W48) and Week 72 (W72).
- Randomized Phase patients: Month 12 (M12), Month 24 (M24), Month 36 (M36), and Month 48 (M48).

The findings of the physical exam may also be recorded on Form #11 at other study visits, but the data is not data entered in the DMS.

- For each question, circle one number to indicate whether the physical examination findings were normal, abnormal, or not evaluated.
- Circle 1 for normal finding(s). Continue to the next question.
- Circle 2 for abnormal finding(s). Provide a brief description for any finding that is abnormal. (Forty spaces including punctuation and spaces are provided in the DMS.) Then continue to the next question.
- Circle 3 if the item was not evaluated during the physical examination. Continue to the next question.
- After answering Question B20, sign the form.

Note: Sections C and D should be completed at every visit that requires a Form #11. The HALT-C staff member who collects the data recorded in Sections C and D must sign the form on page 3.

SECTION C: LIVER RELATED PHYSICAL FINDINGS

A partial physical exam must be completed in order to record data in Section C. The physical exam must be done by an MD, NP, or PA affiliated with the HALT-C trial.

C1. Hepatomegaly
- Consider any liver readily palpable below the right costal margin (RCM) to be enlarged and circle 1 for YES. Continue to Question C1a.
- Circle 2 for NO if there is no hepatomegaly. Skip to Question C2.

C1a. Span (right midclavicular line)
- Indicate the total span in centimeters of the liver in the midclavicular line from top to bottom.
- Round to the nearest centimeter (cm).
- Continue to Question C2.

C2. Splenomegaly
- Circle 1 for YES if the spleen is palpable. Continue to Question C3.
- Circle 2 for NO if the spleen is not palpable. Continue to Question C3.

C3. Ascites
- Circle 1 for YES if ascites is detected. Continue to Question C3a.
- Circle 2 for NO if there is no ascites detected. Skip to Question C4.

C3a. Ascites severity

Characterize the ascites using the following definitions (and confirm by ultrasound)

- Mild: barely detectable. Circle 1 and continue to Question C4.
- Moderate: easily detectable. Circle 2 and continue to Question C4.
- Severe: large (tense) abdomen. Circle 3 and continue to Question C4.

C4. Jaundice

- Circle 1 for PRESENT if there is any physical evidence of jaundice (yellow tinge to the skin, scleral icterus).
- Circle 2 for ABSENT if there is no physical evidence of jaundice.

C5. Encephalopathy

- Circle 1 for YES if encephalopathy is detected. Continue to Question C5a.
- Circle 2 for NO if there is no encephalopathy detected. Skip to Question C6.

C5a. Encephalopathy grade

Circle the corresponding encephalopathy grade using the following definitions then continue to Question C6.

- Grade 1: mild confusion; sleep disorder; forgetfulness; altered mood (euphoria, depression) or behavior; slurred speech; may have asterixis
- Grade 2: lethargy; moderate confusion; drowsiness; inappropriate behavior; asterixis
- Grade 3: stupor (can speak and obey simple commands); somnolent, but arousable; inarticulate speech; marked confusion
- Grade 4: coma

C6. Edema

- Circle 1 for YES if edema is detected. Continue to Question C6a.
- Circle 2 for NO if there is no edema detected. Skip to Section D.

C6a. Edema severity

- Circle the grade corresponding to the edema severity using your best clinical judgment.

Note: Sections C and D should be completed at every visit that requires a Form #11. The HALT-C staff member who collects the data recorded in Sections C and D must sign the form on page 3.

SECTION D: NEW FINDINGS

Section D should be completed by an MD, NP, or PA affiliated with the HALT-C trial.

D1. Are there any new findings at this visit?

- Circle 1 for YES if there are new findings. Continue to Question D2.
- Circle 2 for NO if there are no new findings. After signing, the form is complete.

D2. Specify new findings.

- Provide a brief description of new findings not described elsewhere on this form. (Forty spaces including punctuation and spaces are provided in the DMS.)
- After signing, the form is complete.

- If applicable, Adverse Event Form #60, Serious Adverse Event Form #61, and/or Clinical Outcome Form #63 should be completed.